510(k) Summary for Anemia Calibrator

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K093645

MAR - 5 2010

1. Manufacturer's Name, Address, Telephone, and Contact Person, Date of Preparation:

Manufacturer: Siemens Healthcare Diagnostics, Inc.

500 GBC Drive

Newark, DE 19714

Contact Information: Siemens Healthcare Diagnostics, Inc.

500 GBC Drive

Newark, DE 19714

Attn: A. Kathleen Ennis

Tel: 302-631-9352

Fax: 302-631-6299

Preparation date: November 23, 2009

2. Device Name: Anemia Calibrator

Classification: Class II

Product Code: JIX;

Panel: Clinical Chemistry (75)

3. Identification of the Legally Marketed Device:

Dimension Vista® LOCI 4 Calibrator k071224

4. Device Descriptions:

ANEMIA CAL is a multi-analyte, liquid, frozen bovine serum albumin based product containing ferritin from human liver, Vitamin B12 and Folate

5. **Device Intended Uses:**

Dimension Anemia Calibrator

The ANEMIA CAL is an *in vitro* diagnostic product for the calibration of Ferritin (FERR), LOCI Vitamin B12 (B12) and LOCI Folate (FOL) methods on the Dimension ® EXL™ integrated chemistry system.

6. **Medical device to which equivalence is claimed and comparison information:**
The ANEMIA CAL is substantially equivalent to the Dimension Vista® LOCI 4 Calibrator. ANEMIA CAL, like the predicate, is an *in vitro* diagnostic product intended to be used for the calibration of Ferritin, Vitamin B12 and Folate assays.

7. **Comparative Features Table**

Feature	Predicate Device Dimension Vista® LOCI 4 Calibrator	New Device Dimension® Anemia Calibrator
Similarities		
Intended Use:	LOCI 4 CAL is an *in vitro* diagnostic product for calibration of the Ferritin (FERR), Vitamin B12 (B12) and Folate (FOL) methods on the Dimension Vista® System.	ANEMIA CAL is an *in vitro* diagnostic product for calibration of the Vitamin B12 (B12) and Folate (FOL) methods on the Dimension® EXL™ integrated chemistry system and the Ferritin (FERR) method on the Dimension® clinical chemistry system.
Form:	frozen liquid, bovine serum albumin	frozen liquid, bovine serum albumin
Constituents:	ferritin from human liver, vitamin B12 and folate	ferritin from human liver, vitamin B12 and folate
Traceability of constituents:	ferritin - human serum based anchor pool containing WHO Standard for Ferritin, 3rd IS 94/572 vitamin B12 - Human serum based anchor pool containing USP grade Vitamin B12 folate - human serum based anchor pool containing USP grade folic acid	ferritin - human serum based anchor pool containing WHO Standard for Ferritin, 3rd IS 94/572 vitamin B12 - Human serum based anchor pool containing USP grade Vitamin B12 folate - human serum based anchor pool containing USP grade folic acid
Levels:	5	5
Stability and storage	LOCI 4 CAL is stored at - 20 to -10 ° C LOCI 4 CAL is stable, thawed and unopened for 30 days @ 2 – 8 ° C	ANEMIA CAL is stored at - 25 to - 15 ° C ANEMIA CAL is stable, thawed and unopened for 30 days @ 2 – 8 ° C
Differences		
	LOCI 4 Cal is for use on the Dimension Vista® System.	ANEMIA CAL is for use on the Dimension® EXL™ integrated chemistry system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Siemens Healthcare Diagnostics
c/o Anna M. Kathleen Ennis
500 GBC Drive M/S 514
PO Box 6101
Newark, Delaware 19714

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

MAR 0 5 2010

Re: k093645
Trade Name: Anemia Calibrator
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator.
Regulatory Class: Class II
Product Codes: JIX
Dated: January 20, 2010
Received: January 21, 2010

Dear Ms. Ennis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k093645

Device Name: Anemia Calibrator

Indications for Use:

ANEMIA CAL is an in vitro diagnostic product for the calibration of the LOCI Vitamin B12 (B12)and LOCI Folate(FOL) methods on the Dimension(r) EXL(tm) integrated chemistry system and the Ferritin(FERR) method on the Dimension(r) clinical chemistry system.

Prescription Use XXXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Carol C Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K093645